

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**GENERIC DRUG UTILIZATION IN  
THE MEDICARE PART D  
PROGRAM**



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# *Office of Inspector General*

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## OBJECTIVE

To determine the extent of generic drug utilization in the Medicare Part D program for the first two quarters of 2006.

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## BACKGROUND

Effective January 1, 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 made qualified prescription drug coverage under Medicare Part D (Part D) available to all individuals entitled to benefits under Medicare Part A or enrolled in Medicare Part B. Beneficiaries generally have the option to enroll in either stand-alone prescription drug plans (PDP) or Medicare Advantage prescription drug plans (MA-PD). Under Part D, plans have broad discretion to design plan benefits and develop their drug utilization management tools.

According to the Medicare Board of Trustees, Part D cost the Federal Government \$47 billion in 2006. The cost of the Part D prescription drug program for 2006 was lower than the original estimate of \$59 billion, and future cost estimates have also been reduced, due in part to greater than anticipated generic drug use. Generic drugs cost, on average, 71 percent less than brand name drugs.

Generic drug use is determined by the frequency of generic drug substitution at the pharmacy counter and the prescribing of drugs with no generic drug equivalents. Therefore, in addition to calculating an overall rate of generic drug utilization (i.e., the percentage of all prescriptions that were for generic drugs), this study calculated the following rates that contribute to the overall generic drug utilization rate:

1. Generic drug substitution rate: the percentage of prescriptions for multisource drugs (generic drugs and brand name drugs that have a generic equivalent) that were dispensed as generics.
2. Single-source drug-prescribing rate: the percentage of all prescriptions that were written for single-source drugs (drugs that have no generic equivalent).

These indicators of generic drug utilization were calculated from 341 million prescriptions paid for by Part D plans from January through June 2006.

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## FINDINGS

**Under Part D, generic drugs were dispensed 88 percent of the time when generic substitutes were available.** The generic drug substitution rate measures how often generic drugs were dispensed when generic substitutes were available. For Part D, the overall generic drug substitution rate of 88 percent is similar to the median generic drug substitution rate of 89 percent for State Medicaid programs during 2004.

Generic drug substitution rates were similar across Part D plans, between MA-PDs and PDPs, and across specific types of MA-PDs. However, Part D plans' generic drug substitution rates varied widely within certain therapeutic classes (i.e., groups of drugs that treat the same medical condition).

**Under Part D, 37 percent of prescriptions were written for drugs that have no generic substitutes.** Single-source drugs have no generic substitutes. Therefore, the proportion of prescriptions that are written for them (i.e., the single-source drug-prescribing rate) limits Part D plans' opportunities for generic drug utilization. For Part D, the overall single-source drug-prescribing rate of 37 percent is similar to the median single-source drug-prescribing rate of 41 percent for State Medicaid programs during 2004.

Single-source drug-prescribing rates varied across Part D plans, ranging from 14 percent to 59 percent. Single-source drug-prescribing rates were similar between MA-PDs and PDPs but varied across specific types of MA-PDs. Part D plans' single-source drug-prescribing rates also varied widely within certain therapeutic classes of drugs. For four therapeutic classes—antiulcer/gastrointestinal preparations, cardiovascular preparations, lipotropics, and psychostimulants/antidepressants—plans' single-source drug-prescribing rates varied by more than 95 percentage points.

**Under Part D, 56 percent of all drugs dispensed were generics.** The generic drug utilization rate is the percentage of all prescriptions dispensed that were generics. For Part D, the overall generic drug utilization rate of 56 percent is similar to the median generic drug utilization rate of 54 percent for State Medicaid programs during 2004.

Generic drug utilization rates varied across Part D plans, ranging from 37 percent to 83 percent. Generic drug utilization rates were similar between MA-PDs and PDPs but varied across specific types of MA-PDs.

Variation in the rate of single-source drug prescribing primarily accounted for variation in generic drug utilization. Generic drug utilization was highest in plans for which single-source drug prescribing was lowest; conversely, generic drug utilization was lowest in plans for which single-source drug prescribing was highest.

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## CONCLUSION

Overall, Part D achieved a high level of generic drug use during the first two quarters of calendar year 2006 that was similar to the level of generic drug use achieved by State Medicaid programs in 2004. High rates of generic drug use help minimize costs to beneficiaries and keep Part D affordable over the long term.

Despite high overall generic drug use, generic drug utilization rates varied among plans. At the low end, one Part D plan achieved only a generic drug utilization rate of 37 percent, while one Part D plan achieved a rate of 83 percent.

Variation in generic drug utilization rates is strongly related to variation in single-source drug prescribing, but not to generic drug substitution. In fact, Part D may have already achieved most of the growth in generic drug utilization possible through increasing generic drug substitution.

To achieve increases in generic drug utilization, Part D plans may realize greater gains by encouraging the prescribing of multisource drugs because they offer the opportunity to dispense a generic drug. In particular, Part D plans could focus on therapeutic classes that exhibited wide ranges of single-source drug-prescribing rates.

Lower single-source drug prescribing could be realized through the inclusion of multisource drugs in a Part D plan's formulary, educating prescribers, or other means such as drug utilization management tools. However, such efforts must be undertaken with caution to ensure that beneficiaries maintain access to appropriate treatment.

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In response to our draft report, the Centers for Medicare & Medicaid Services (CMS) generally concurred with our findings. CMS noted differences between our calculation and CMS's calculation of generic drug utilization and suggested that differences may be because of CMS's

## E X E C U T I V E   S U M M A R Y

inclusion of multisource brand name drugs in its measure of generic drug utilization. CMS also raised questions regarding the period under review and differences in generic drug utilization between MA-PDs and stand-alone PDPs.

With respect to the issue of different calculations of generic drug utilization, CMS suggested that we include multisource brand name drug utilization data in our report and stated that including these data would narrow the gap between our and CMS's calculations of generic drug utilization rates. We did not include multisource brand name drug utilization data in our measure of generic drug utilization because this would be inconsistent with the definition of generic drugs as used in this report. We note that the analysis presented in this report is consistent with previous work on generic drug utilization conducted by the Office of Inspector General.

In addition, our calculation of generic drug utilization reflects the current CMS regulatory definition for generic drugs. Pursuant to CMS's regulations for Part D, a drug is defined as generic or brand depending on the drug application type. Multisource brand name drugs are considered brand name drugs under this definition.

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## OBJECTIVE

To determine the extent of generic drug utilization in the Medicare Part D program for the first two quarters of 2006.

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## BACKGROUND

### **The Medicare Prescription Drug Benefit**

Effective January 1, 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) made qualified prescription drug coverage under Medicare Part D (Part D) available to all individuals entitled to benefits under Medicare Part A or enrolled in Medicare Part B.<sup>1</sup> Beneficiaries have the option to enroll in (1) a stand-alone prescription drug plan (PDP) and receive all other Medicare benefits through traditional Medicare fee-for-service, or (2) a Medicare Advantage (MA) plan and receive all Medicare benefits (including drug coverage) through managed care.<sup>2</sup>

The MA plans that offer Part D coverage are referred to as Medicare Advantage prescription drug plans (MA-PD). Some examples of MA plans that offer Part D coverage include Private Fee-For-Service Plans, Health Maintenance Organizations, and Preferred Provider Organizations.

Enrollment in PDPs and MA-PDs has risen steadily since the inception of Part D. In January 2006, the Centers for Medicare & Medicaid Services (CMS) reported that over 14 million Medicare beneficiaries had enrolled in PDPs or MA-PDs. By January 2007, enrollment increased to almost 24 million beneficiaries, with over 15 million enrolled in PDPs and over 8 million enrolled in MA-PDs.<sup>3</sup>

### **Generic Drugs**

There are three types of drugs: single-source, brand name multisource, and generic. A single-source drug is a brand name drug with no generic drug equivalents. A brand name multisource drug is a brand name drug with generic drug equivalents.

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<sup>1</sup> 42 U.S.C. § 1395w-101 (2003).

<sup>2</sup> 42 U.S.C. § 1395w-101(a) (2003).

<sup>3</sup> Centers for Medicare & Medicaid Services. "Total Medicare Beneficiaries with Drug Coverage Data" (v.01.16.07). January 17, 2007.

A generic drug is chemically identical to its brand name counterpart, with the same therapeutic effect and risk-benefit profile. To be approved by the Food and Drug Administration (FDA), a generic drug must contain the same amount(s) of the same active ingredient(s) as the brand name product.<sup>4</sup> The generic drug must also be the same strength, be available in the same dosage, have the same route of administration, and have essentially the same labeling as the brand name drug. FDA gives an A rating to a generic drug that it finds to be pharmaceutically and therapeutically equivalent to the drug's brand name counterpart. Only A-rated generic drugs may be substituted by a pharmacist without permission from the prescribing physician.

#### **Part D Expenditures and Potential Savings from Generic Drugs**

According to the Medicare Board of Trustees, Part D cost the Federal Government \$47 billion in 2006.<sup>5</sup> The Medicare Board of Trustees also estimated the cost of Part D, from 2007 to 2016, to be between \$823 billion and almost \$1 trillion.<sup>6</sup>

The cost of the Part D prescription drug program for 2006 was lower than the original estimate of \$59 billion,<sup>7</sup> and future cost estimates have also been reduced, due in part to greater than anticipated generic drug use.<sup>8</sup> In testimony before the Senate Special Committee on Aging, CMS emphasized the role that generic drugs played in lowering the costs of Part D for the Federal Government.<sup>9</sup>

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<sup>4</sup> Food and Drug Administration, "What are Generic Drugs?" Available online at <http://www.fda.gov/cder/ogd/#Introduction>. Accessed on June 12, 2007.

<sup>5</sup> The Medicare Board of Trustees. "2007 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds" at 5. Available online at <http://www.cms.hhs.gov/ReportsTrustFunds/>. Accessed on May 1, 2007.

<sup>6</sup> *Id.* at 115.

<sup>7</sup> The Medicare Board of Trustees. "2006 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds" at 22. Available online at <http://www.cms.hhs.gov/ReportsTrustFunds/>. Accessed on July 27, 2007.

<sup>8</sup> The Medicare Board of Trustees. "2007 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds" at 112-113. Available online at <http://www.cms.hhs.gov/ReportsTrustFunds/>. Accessed on May 1, 2007.

<sup>9</sup> Testimony of Centers for Medicare & Medicaid Services former Administrator Dr. Mark McClellan before the Senate Special Committee on Aging, September 21, 2006. Available online at <http://www.cms.hhs.gov/apps/media/press/testimony.asp?Counter=1971>. Accessed on February 6, 2007.

Generally, generic drugs are cheaper than single-source and brand name multisource drugs. According to the National Association of Chain Drug Stores, in 2005 the average brand name drug prescription cost \$101.71, while the average generic drug prescription cost \$29.82—a 71 percent difference.<sup>10</sup>

Using generic rather than brand name drugs may also reduce beneficiaries' out-of-pocket costs for premiums, copayments, or coinsurance. Premiums are based on estimates of a number of factors but are primarily driven by the Part D plan's expected drug costs and drug coverage. In addition, beneficiaries are typically either responsible for a percentage of the cost of their prescription drugs or a set copayment, which may be lower for generic drugs than for brand name drugs.

Beneficiaries are responsible for 100 percent of their drug costs in the coverage gap (either out-of-pocket or through supplemental coverage) if they are enrolled in Part D plans that do not provide coverage through the coverage gap. Under the 2006 standard Part D benefit package, once beneficiaries reached \$750 in out-of-pocket expenses, standard plans would not cover any portion of the beneficiaries' drug costs until the beneficiaries spent an additional \$2,850 in out-of-pocket expenses. The Kaiser Family Foundation projected that approximately 4 million beneficiaries would incur costs in the coverage gap during 2006.<sup>11</sup>

Given the potential savings for the Federal Government and beneficiaries, Congress and CMS have shown interest in the level of generic drug use under Part D. In January 2007, Congress requested that the Office of Inspector General (OIG) conduct an evaluation to determine the extent of generic drug utilization under Part D.

### **Part D Drug Coverage and Utilization Management**

Part D plans have broad discretion to design plan benefits and formularies.<sup>12</sup> Formularies are one of the main tools that Part D plans can use to drive utilization, including generic drug use. Formularies are a specified set of prescription drugs covered (i.e., paid for) by drug plans.

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<sup>10</sup> National Association of Chain Drug Stores. Available online at <http://www.nacds.org/wmspage.cfm?parm1=507>. Accessed on January 5, 2007.

<sup>11</sup> The Henry J. Kaiser Foundation. "Medicare Fact Sheet: The Medicare Prescription Drug Benefit," November 2006. Available online at <http://www.kff.org/medicare/upload/7044-05.pdf>. Accessed on June 25, 2007.

<sup>12</sup> 42 U.S.C. § 1395w-111(e)(2)(D) (2003).

Beneficiaries are responsible for the full cost of drugs not included on their Part D plan's formulary, unless they apply for and are granted an exception.

CMS provides oversight of Part D plans' formularies to ensure that Part D plan formularies meet legal requirements. Specifically, CMS requires that formularies include at least two drugs in each approved category and class (unless only one drug in a particular category or class is available).<sup>13</sup> CMS also required that Part D plans not restrict access to necessary drugs for the first 3 months of Part D (until March 31, 2006). During this transition period, Part D plans were required to provide access to drugs that beneficiaries were previously taking, regardless of whether the drugs were covered under the Part D plan's formulary. In 2007, during the first 90 days of a beneficiary's enrollment, plans must provide a one-time supply of drugs that beneficiaries were previously taking that are not on the plan formulary. Open enrollment for 2007 ended December 31, 2006.

In addition to formularies, Part D plans can use drug utilization management tools to influence beneficiary drug utilization. The MMA requires each Part D plan to have a drug utilization management program that includes incentives to reduce costs when medically appropriate, such as through the use of generic and brand name multisource drugs.<sup>14</sup> Some of the tools employed by Part D plans to increase generic drug use include step therapy, prior authorization for brand name drugs, tiered formularies that charge less expensive copayments for generic drugs, and mandatory generic drug substitution.<sup>15</sup>

In addition, Part D plans encourage generic drug utilization at pharmacies by making prices of generic and brand name drugs available for comparison to beneficiaries. According to the MMA, each Part D plan should ensure that its network pharmacies inform beneficiaries of

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<sup>13</sup> 42 CFR § 423.120(b)(2)(i) (2005).

<sup>14</sup> 42 U.S.C. § 1395w-104(c)(1)(A) (2003).

<sup>15</sup> For more information on Part D formulary requirements, refer to the Medicare Part D Manual, Chapter 6-Part D Drugs and Formulary Requirements. Available online at [http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyRequirements\\_03.09.07.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyRequirements_03.09.07.pdf). Accessed on June 25, 2007.

the cost differential between the price of the prescribed drug and the lowest cost generic drug equivalent.<sup>16</sup>

### **Generic Drug Utilization**

Generic drug utilization is the result of a physician originally prescribing a generic drug or a pharmacist substituting a generic drug for a brand name multisource drug at the pharmacy. The rate at which these events occur is often referred to as the generic drug dispensing rate or generic usage rate. One industry report shows that generic drugs accounted for 57 percent of all retail drugs dispensed nationally during 2006.<sup>17</sup>

During testimony before the Senate Special Committee on Aging, CMS reported generic drug usage among all Part D plans at 60 percent during the first two quarters of calendar year (CY) 2006.<sup>18</sup> CMS also reported on its Web site a generic drug utilization rate of 66 percent for MA-PDs and 57 percent for PDPs.<sup>19</sup>

### **Generic Drug Substitution**

Generic drug substitution is only possible when a health care provider prescribes a multisource drug (i.e., a brand name multisource drug or its associated generic equivalent). Generic drug substitution occurs when a physician prescribes the generic version of a multisource drug rather than its brand name equivalent or when a pharmacist receives a prescription for a brand name multisource drug and dispenses the generic version instead.

Theoretically, Part D plans should be able to achieve high generic drug substitution rates because generic drugs are chemically and therapeutically equivalent to their brand name multisource counterparts. There are situations in which generic drug substitution is not possible, but these circumstances are rare. For example, a small

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<sup>16</sup> 42 U.S.C. § 1395w-104(k)(1)(2003).

<sup>17</sup> IMS Health, Available online at

[http://imshealth.com/vgn/images/portal/CIT\\_40000873/25/19/81829004MedicarePartD-TheFirstYear.pdf](http://imshealth.com/vgn/images/portal/CIT_40000873/25/19/81829004MedicarePartD-TheFirstYear.pdf). Accessed on August 16, 2007.

<sup>18</sup> Testimony of Centers for Medicare & Medicaid Services former Administrator Dr. Mark McClellan before the Senate Special Committee on Aging, September 21, 2006. Available online at <http://www.cms.hhs.gov/apps/media/press/testimony.asp?Counter=1971>. Accessed on February 6, 2007.

<sup>19</sup> Centers for Medicare & Medicaid Services. "Part D Generic Dispensing Rates" (v.02.08.07). Available online at [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/06\\_PerformanceData.asp#TopOfPage](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp#TopOfPage). Accessed on February 12, 2007.

percentage of patients may medically require the brand name multisource drug if they are allergic to an inactive ingredient such as a dye or binder found in the generic version. Additionally, disruptions in the supply chain may mean that a pharmacy does not have the generic version of a drug in stock and must dispense the brand name multisource drug.<sup>20</sup> Despite these potential barriers, generic drug substitution rates at or above 90 percent have been reported for the private sector.<sup>21</sup>

Generic drug substitution is an attractive option for cost containment, because it can save money without adversely affecting beneficiaries' health. Although generic drug substitution generally achieves savings, it may not save money in all circumstances. Part D plans negotiate with prescription drug manufacturers to obtain rebates or other price concessions for drugs on their formularies. In some instances, a Part D plan may be able to negotiate a lower net price for a brand name multisource drug than for its generic drug equivalent.

### **Single-Source Drug Prescribing**

The rate at which single-source drugs are prescribed depends on a number of factors. These include prescriber habits, patient demand for newer or highly advertised drugs, and therapeutic advances associated with newer brand name drugs. For some conditions, single-source drugs are the only available treatment. Therefore, the health status and preferences of enrollees may lead to differences across plans in the rates of single-source drug prescribing.

### **Related Office of Inspector General Work**

In July 2006, OIG determined the extent of generic drug utilization in State Medicaid programs during CY 2004.<sup>22</sup> OIG found that State Medicaid programs demonstrated high generic utilization. However, certain therapeutic classes, which categorize drugs according to their most common intended use, showed substantial variation in States' generic drug substitution rates. In addition, this study found a

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<sup>20</sup> Food and Drug Administration. "Drug Shortages." Available online at <http://www.fda.gov/cder/drug/shortages/>. Accessed on May 14, 2007.

<sup>21</sup> Pharmaceutical Care Management Association, "The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs," Testimony of Mark Merrit Before the United States Senate Special Committee on Aging, July 20, 2006.

<sup>22</sup> Office of Inspector General. "Generic Drug Utilization in State Medicaid Programs", OEI-05-05-00360, July 2006. Available online at <http://www.oig.hhs.gov/oei/reports/oei-05-05-00360.pdf>. Accessed on June 25, 2007.

correlation between single-source drug-prescribing rates and generic drug utilization rates across States.

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## METHODOLOGY

### Scope

This study determines the extent of generic drug use for the Part D program during the first two quarters of CY 2006. It does not analyze the impact of Part D plans' formularies or utilization management tools on generic drug use. This study also does not determine what generic drug substitution, single-source drug prescribing, or generic drug utilization rates are appropriate. Instead, by calculating different indicators of generic drug use and comparing Part D plans to one another, this study explores potential avenues for increasing generic drug use.

### Data Sources

To conduct this study, we used Prescription Drug Event (PDE) data and First DataBank product information. Part D plans submit PDE data to CMS. Each event included in the PDE data represents a claim for the dispensing of a drug or medical supply.<sup>23</sup> These data contain FDA's National Drug Code (NDC), a three-part universal identifier that specifies the drug's manufacturer, name, dosage form, strength, and package size. The PDE data also include whether the drug is covered under the standard Part D benefit, whether the drug is an over-the-counter drug, prescriber information, and where the prescription was dispensed.

First DataBank is a third-party provider of drug pricing and product information. Among other things, it provides information by the NDC, the drug name, standard therapeutic class, and whether the drug is a single-source drug, a brand name multisource drug, or a generic drug.

### Data Collection

We collected all PDE data submitted by Part D plans from January 2006 through March 2007. Part D plans could submit PDE data for CY 2006 through the end of June of 2007. By collecting all PDE data for this period, we increased the likelihood that we captured a

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<sup>23</sup> Medical supplies allowable under Part D include those associated with the injection of insulin.

substantial majority of all PDE data for the first two quarters of CY 2006.

**Data Analysis**

Our analysis included those PDE data with a date of service between January 1 and June 30, 2006. This resulted in 404 million events from 547 Part D plans.

We merged the 404 million events with the First DataBank drug product information to obtain additional information about the dispensed drug. To improve the accuracy of our calculations, we removed events that could affect our analysis. For example, we removed PDE claims for medical supplies, for nonprescription drugs, and multiple submissions for the same dispensing event. This process left 341 million events (84 percent of the total submissions) from 528 Part D plans (97 percent of plans) in our analysis. See Table 1 for the number of plans and claims for MA-PDs, PDPs, and Employer/Union Contract PDPs. See Appendix A for additional methodology and information on the types and number of claims removed.

<b>Table 1: Number of Plans and Claims for MA-PDs, PDPs, and Employer/Union Contract PDPs</b>		
	<b>Number of Plans</b>	<b>Number of Claims</b>
MA-PD	437	79,366,113
PDP	83	260,224,786
Employer/Union Contract PDP	8	1,544,259
<b>Total</b>	<b>528</b>	<b>341,135,158</b>

Source: OIG analysis of January-June 2006 PDE data, 2007.

For Part D in the aggregate and for each specific Part D plan, we calculated the generic drug utilization rate, as well as two indicators that contribute to overall generic drug utilization: the generic drug substitution rate and the single-source drug-prescribing rate. We then determined the median across plans for each rate.

We also calculated each Part D plans' generic drug substitution rate and single-source drug-prescribing rate for the 10 standard therapeutic classes with the most claims. We used the generic sequence number

associated with each NDC to determine the therapeutic class for each NDC.<sup>24</sup>

To determine whether generic drug use was affected during the transition period by the requirement for Part D plans to provide beneficiaries' access to drugs they were previously taking, we calculated and compared the overall generic drug utilization rate by month for each of the 6 months.

*Generic Drug Substitution Rate.* To determine the generic drug substitution rate, we divided the total of all FDA A-rated generic drug prescriptions by the total of multisource prescriptions (both brand name multisource and FDA A-rated generic). We only considered generic drugs with an FDA A-rating as substitutable.

$$\frac{\text{FDA A-Rated Generic Drug Prescriptions}}{\text{Multisource Drug Prescriptions (Brand Name Multisource + FDA A-Rated Generic Drugs)}}$$

*Single-Source Drug-Prescribing Rate.* We calculated the single-source drug-prescribing rate by dividing the total of all single-source drug prescriptions by the total of all prescriptions. The single-source drug-prescribing rate is useful because it inherently limits the rate at which generic drugs can be dispensed.

$$\frac{\text{Single-Source Drug Prescriptions}}{\text{All Drug Prescriptions (Single-Source + Brand Name Multisource + Generic Drugs)}}$$

*Generic Drug Utilization Rate.* We calculated the generic drug utilization rate by dividing the total number of generic drug prescriptions by the total of all prescriptions. This is also called the generic dispensing or generic usage rate.

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<sup>24</sup> In the First DataBank product data, the generic sequence number represents a generic drug formulation identifier that groups drug products by the set of ingredients, route of administration, dosage form, and strength of the drug.

### **Generic Drug Utilization Rate**

Generic Drug Prescriptions

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All Drug Prescriptions (Single-Source + Brand Name Multisource  
+ Generic Drugs)

CMS calculates a generic drug utilization rate that is not directly comparable to the generic drug utilization rate presented in this report. CMS also calculates generic drug utilization rates for Part D plans using data different from those used in this report. CMS bases its calculations on aggregate utilization data reported by each plan on a quarterly basis,<sup>25</sup> reflecting a snapshot of claims available to Part D plans at the time of their submission. The rates in this report are calculated using data from January through June 2006, which were submitted during a 15-month period. In addition, plans have the option of using different methodologies to identify generic and brand name drugs.<sup>26</sup> Plans do not specify the methodology they use in reporting their generic drug utilization.

*Comparing Plans' Generic Drug Use.* Using the three rates we calculated for each Part D plan, we compared generic drug use across Part D plans. In addition, we analyzed and compared the rates for all MA-PD plans as a group to the rates for all PDP plans as a group.

We further analyzed MA-PD generic drug use to detect any differences among the different types of plans categorized as MA-PDs. See Appendix B for a full list of MA-PD plans.

*Comparing Part D Generic Drug Use to Medicaid Generic Drug Use.* As a benchmark for the generic drug use rates that we found under Part D, we compared median plan rates under Part D to median rates among State Medicaid programs. For purposes of the comparison to Medicaid, we used the previous OIG analysis of generic drug use rates under Medicaid during CY 2004. The CY 2004 Medicaid data included prescription drug utilization data for dual eligible beneficiaries. Most of the 6 million dual

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<sup>25</sup> Part D plans are responsible for reporting these data using definitions of generic and brand name drugs pursuant to 42 CFR § 423.4.

<sup>26</sup> Pursuant to the January 25, 2006, Medicare Part D Reporting Requirements, Part D plans were to use First DataBank or Medispan generic drug classifications to identify generic drugs.

## I N T R O D U C T I O N

eligibles who received prescription drug coverage under Medicaid in CY 2004 now receive their coverage under Part D.

### **Data Limitations**

Because CMS policy allowed Part D plans to submit PDE data for CY 2006 through June 2007, our analysis may lack some claims from the first two quarters of CY 2006. However, there is no evidence to suggest that any outstanding PDE data are significantly weighted toward generic or single-source drugs.

Because of enrollment errors, some plans paid for prescription drugs for beneficiaries enrolled in other plans. Although our data reflect these payment errors, they accurately reflect the drugs dispensed, which are determined by the formulary of the plan that paid for the prescription drug claims. For an analysis of generic drug use, the significant factor is the type of drug allowed under the plans' formularies and not which plan paid for the drug.

### **Standards**

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

## ► FINDINGS

### **Under Part D, generic drugs were dispensed 88 percent of the time when generic substitutes were available**

The generic drug substitution rate measures how often generic drugs are dispensed when generic substitutes are available. For

Part D, the overall generic drug substitution rate was 88 percent during the first two quarters of CY 2006. The median generic drug substitution rate by Part D plans was 89 percent.

Consistent with this analysis, a previous OIG study found that State Medicaid programs had a median generic drug substitution rate of 89 percent during 2004. Generic drug substitution rates at or above 90 percent have been achieved outside of Medicare and Medicaid.<sup>27</sup>

#### **Generic drug substitution rates were similar across Part D plans**

Most Part D plans' generic drug substitution rates were clustered tightly around the median Part D plan rate of 89 percent. Of the 528 Part D plans analyzed, 468 had generic drug substitution rates within 5 percentage points of the median Part D plan rate of 89 percent. The overall range for plans' generic drug substitution rates was 70 percent to 98 percent. See Table 2 for more details on Part D plan generic drug substitution rates.

**Table 2: Generic Drug Substitution Rates Across Part D Plans During the First Two Quarters of CY 2006**

Median Plan Generic Drug Substitution Rate	Lowest Plan Generic Drug Substitution Rate	Highest Plan Generic Drug Substitution Rate	Range of Plan Generic Drug Substitution Rates in the Middle 50 Percent of Plans
89%	70%	98%	87%-90%

Source: OIG analysis of January-June 2006 PDE data, 2007.

#### **Median generic drug substitution rates were similar between MA-PDs and PDPs and across types of MA-PDs**

The median plan generic drug substitution rates for MA-PDs, as a group, and PDPs were similar. The median generic drug substitution rate for MA-PDs was 89 percent; it was 87 percent for PDPs.

<sup>27</sup> Pharmaceutical Care Management Association, "The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs," Testimony of Mark Merrit Before the United States Senate Special Committee on Aging, July 20, 2006.

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See Table 3 for more details on MA-PD and PDP generic drug substitution rates.

<b>Table 3: Generic Drug Substitution Rates for MA-PDs and PDPs During the First Two Quarters of CY 2006</b>				
	<b>Median Plan Generic Drug Substitution Rate</b>	<b>Lowest Plan Generic Drug Substitution Rate</b>	<b>Highest Plan Generic Drug Substitution Rate</b>	<b>Range of Plan Generic Drug Substitution Rates in the Middle 50 Percent of Plans</b>
MA-PD	89%	74%*	98%	87%-91%
PDP	87%	70%*	93%*	86%-89%
* The MA-PD with the lowest generic drug substitution rate had less than 100 claims. The PDP with the lowest generic drug substitution rate had less than 200 claims. The PDP with the highest generic drug substitution rate had less than 400 claims.				

Source: OIG analysis of January-June 2006 PDE data, 2007.

An analysis by MA-PD plan types also shows minimal variation across generic drug substitution rates, ranging from 87 percent to 91 percent. See Appendix B for a breakout of generic drug substitution rates by MA-PD type.

### **Generic drug substitution rates varied widely within therapeutic classes of drugs**

Eight of the top 10 therapeutic classes had a 50 or greater percentage point difference between the lowest and highest rates. Among the 10 classes of drugs we reviewed, the therapeutic class with the smallest variation between the lowest and highest plan rates, diuretics, still had a 25 percentage point range.

In each of the top 10 therapeutic classes we reviewed, at least two Part D plans achieved generic drug substitution rates of 100 percent. In fact, 159 plans achieved rates of 100 percent in one or more of these therapeutic classes. However, in each therapeutic class some Part D plans achieved much lower rates of generic drug substitution. In two therapeutic classes, thyroid preparations and anticoagulants, the ranges between the Part D plan with the lowest generic drug substitution rate and the Part D plan with the highest rate were 99 and 86 percentage points, respectively. Given that several Part D plans achieved 100 percent generic drug substitution rates in each of the 10 therapeutic classes, opportunities may exist for other Part D plans to increase their rates of generic drug substitution.

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Table 4 presents information on the generic drug substitution rates across Part D plans for the 10 most dispensed therapeutic classes.

<b>Table 4: Generic Drug Substitution Rates for Selected Therapeutic Classes During the First Two Quarters of CY 2006</b>					
<b>Therapeutic Class</b>	<b>Median Plan Generic Drug Substitution Rate</b>	<b>Minimum Plan Generic Drug Substitution Rate</b>	<b>Maximum Plan Generic Drug Substitution Rate</b>	<b>Percentage Point Difference Between Minimum and Maximum Plan Rate</b>	<b>Total Claims</b>
Thyroid preparations	72%	1%*	100%	99%	9,457,235
Anticoagulants	96%	14%	100%	86%	10,977,071
Lipotropics	97%	29%	100%	71%	24,103,932
Diabetic therapy	77%	33%	100%	67%	21,196,162
Cardiovascular preparations	81%	34%	100%	66%	35,225,704
Psychostimulants-Antidepressants	93%	43%	100%	57%	20,462,115
Narcotic analgesics	96%	48%	100%	52%	17,275,975
Antiulcer/gastrointestinal preparations	99%	50%	100%	50%	14,543,189
Hypotensives	93%	68%	100%	32%	33,061,444
Diuretics	98%	75%	100%	25%	19,353,082

\* The plan with the lowest generic drug substitution rate appears to be an outlier. The generic drug substitution rate for the plan with the next lowest rate is 12 percent.

Source: OIG analysis of January-June 2006 PDE data, 2007.

**Under Part D, 37 percent of prescriptions were written for drugs that have no generic substitutes**

Single-source drugs have no generic drug substitutes. For Part D, single-source drugs comprised 37 percent of all prescriptions filled during the first

two quarters of CY 2006. When a single-source drug is prescribed, a generic drug cannot be dispensed. Thus, for this 37 percent of prescriptions, there was no opportunity to dispense a generic drug. The median rate by Part D plan was 35 percent.

In comparison, OIG previously found that State Medicaid programs had a median single-source drug-prescribing rate of 41 percent during CY 2004.

**Single-source drug-prescribing rates varied widely across Part D plans**

Part D plans' single-source drug-prescribing rates varied, ranging from 14 percent to 59 percent. For five Part D plans, single-source drugs were prescribed 50 percent of the time or more. These Part D plans were more limited than others in their opportunities to dispense generic drugs. See Table 5 for more details on Part D plans' single-source drug-prescribing rates.

<b>Table 5: Single-Source Drug-Prescribing Rates Across Part D Plans During the First Two Quarters of CY 2006</b>			
<b>Median Plan Single-Source Drug-Prescribing Rate</b>	<b>Lowest Plan Single-Source Drug-Prescribing Rate</b>	<b>Highest Plan Single-Source Drug-Prescribing Rate</b>	<b>Range of Plan Single-Source Drug-Prescribing Rates in the Middle 50 Percent of Plans</b>
35%	14%	59%*	31%-39%
* The plan with the highest single-source drug-prescribing rate had very low enrollment and less than 50 claims.			

Source: OIG analysis of January-June 2006 PDE data, 2007.

**Median single-source drug-prescribing rates were similar between MA-PDs and PDPs but varied across types of MA-PDs**

When comparing MA-PDs to PDPs, median single-source drug-prescribing rates were similar. The median single-source drug-prescribing rate for MA-PDs was 34 percent, only 5 percentage points lower than the median PDP rate of 39 percent. However, specific MA-PDs achieved lower single-source drug-prescribing rates than PDPs. Forty-nine MA-PDs were able to limit their single-source drug-prescribing rates to 25 percent or below. No PDP had a single-source drug-prescribing rate below 27 percent. On the other hand, a similar number of MA-PDs (two) and PDPs (three) had rates at or above 50 percent. See Table 6 on the following page for more details on MA-PD and PDP single-source drug-prescribing rates.

<b>Table 6: Single-Source Drug-Prescribing Rates for MA-PDs and PDPs During the First Two Quarters of CY 2006</b>				
	<b>Median Plan Single-Source Drug-Prescribing Rate</b>	<b>Lowest Plan Single-Source Drug-Prescribing Rate</b>	<b>Highest Plan Single-Source Drug-Prescribing Rate</b>	<b>Range of Plan Single-Source Drug-Prescribing Rates in the Middle 50 Percent of Plans</b>
MA-PD	34%	14%	53%	29%-37%
PDP	39%	27%	59%*	37%-41%
* The PDP with the highest single-source drug-prescribing rate had very low enrollment and less than 50 claim submissions.				

Source: OIG analysis of January-June 2006 PDE data, 2007.

When comparing rates across specific types of MA-PDs, median single-source prescribing rates showed variation. The lowest median single-source prescribing rate by plan type was 27 percent, while the highest median by plan type was 41 percent. See Appendix B for a breakout of single-source prescribing rates by MA-PD plan type.

**Single-source drug-prescribing rates varied widely within therapeutic classes of drugs**

Part D plan single-source drug-prescribing rates varied widely within 9 of the top 10 therapeutic classes that we reviewed. The range of single-source drug-prescribing rates within these therapeutic classes was most pronounced in two classes: antiulcer/gastrointestinal preparations and cardiovascular preparations. Part D plans' single-source drug-prescribing rates in these two therapeutic classes varied by 99.5 and 99 percentage points, respectively.

In fact, within five therapeutic classes, some Part D plans had no opportunity for generic drug utilization because they had single-source drug-prescribing rates of 100 percent. On the other hand, within all therapeutic classes, at least one Part D plan was able to limit single-source drug prescribing to 14 percent or below. The ability of some plans to attain low single-source drug-prescribing rates in all 10 therapeutic classes indicates that each therapeutic class had multisource drugs available. The wide variation within each therapeutic class suggests that Part D plans may have the opportunity to decrease single-source drug prescribing and increase their rates of generic drug utilization.

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Table 7 presents information on the single-source drug-prescribing rates for the 10 most dispensed therapeutic classes.

<b>Table 7: Single-Source Drug-Prescribing Rates for Selected Therapeutic Classes During the First 2 Quarters of CY 2006</b>					
<b>Therapeutic Class</b>	<b>Median Plan Single-Source Drug-Prescribing Rate</b>	<b>Minimum Plan Single-Source Drug-Prescribing Rate</b>	<b>Maximum Plan Single-Source Drug-Prescribing Rate</b>	<b>Percentage Point Difference Between Minimum and Maximum Plan Rate</b>	<b>Total Claims</b>
Antiulcer/gastrointestinal preparations	53%	0.48%	100%	99.5%	14,543,189
Cardiovascular preparations	23%	1%	100%*	99%	35,225,704
Lipotropics	80%	4%	100%	96%	24,103,932
Psychostimulants-Antidepressants	37%	4%	100%	96%	20,462,115
Anticoagulants	50%	14%	100%	86%	10,977,071
Hypotensives	30%	2%	75%	73%	33,061,444
Diabetic Therapy	32%	4%	64%	60%	21,196,162
Narcotic analgesics	1%	0.01%	60%	60%	17,275,975
Thyroid preparations	0.42%	0.01%	29%	29%	9,457,235
Diuretics	0.41%	0.01%	4%	4%	19,353,082
*The plan with the highest single-source drug-prescribing rate in this class had low enrollment and few claims. The next highest plan single-source drug-prescribing rate was 50 percent.					

Source: OIG analysis of January-June 2006 PDE data, 2007.

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**Under Part D, 56 percent of all drugs dispensed were generics**

The generic drug utilization rate is the percentage of all prescriptions dispensed that were

generic drugs regardless of whether generic drugs were available. The overall generic drug utilization rate for Part D was 56 percent during the first two quarters of CY 2006. The overall generic drug utilization rate was consistent from month to month during these 6 months under Part D, including during the initial transition period from January through the end of March 2006. The median generic drug utilization rate by Part D plan was 58 percent.

In comparison, a previous OIG study found that State Medicaid programs had a median generic drug utilization rate of 54 percent during CY 2004. Moreover, one recent industry report shows that generic drugs accounted for 57 percent of all retail drugs dispensed nationally during 2006.<sup>28</sup>

**Generic drug utilization rates varied widely across Part D plans**

Part D plans' rates of generic drug utilization varied substantially from the median plan rate of 58 percent. The lowest Part D plan generic drug utilization rate was 37 percent, while the highest was 83 percent. Eleven Part D plans were able to achieve generic drug utilization rates at or above 75 percent. On the other hand, three Part D plans had generic drug utilization rates at or below 40 percent. See Table 8 for more details on Part D plan generic drug utilization rates.

**Table 8: Generic Drug Utilization Across Part D Plans During the First Two Quarters of CY 2006**

Median Plan Generic Drug Utilization Rate	Lowest Plan Generic Drug Utilization Rate	Highest Plan Generic Drug Utilization Rate	Range of Plan Generic Drug Utilization Rates in the Middle 50 Percent of Plans
58%	37%	83%	53%-62%

Source: OIG analysis of January-June 2006 PDE data, 2007.

<sup>28</sup> IMS Health, Available online at [http://imshealth.com/vgn/images/portal/CIT\\_40000873/25/19/81829004MedicarePartD-TheFirstYear.pdf](http://imshealth.com/vgn/images/portal/CIT_40000873/25/19/81829004MedicarePartD-TheFirstYear.pdf). Accessed on August 16, 2007.

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**Median generic drug utilization rates were similar between MA-PDs and PDPs but varied across types of MA-PDs**

When comparing MA-PDs, as a group, and PDPs, rates of generic drug use were similar. The median generic drug utilization rate for MA-PDs was 59 percent, only 6 percentage points higher than the median PDP plan rate of 53 percent. Specific MA-PDs were able to achieve higher generic drug utilization rates than PDPs. Thirty MA-PDs had generic drug utilization rates above 70 percent. The highest generic utilization rate for a PDP was 68 percent. See Table 9 for more details on MA-PD and PDP generic drug utilization rates.

<b>Table 9: Generic Drug Utilization Rates for MA-PDs and PDPs During the First Two Quarters of CY 2006</b>				
	<b>Median Plan Generic Drug Utilization Rate</b>	<b>Lowest Plan Generic Drug Utilization Rate</b>	<b>Highest Plan Generic Drug Utilization Rate</b>	<b>Range of Plan Generic Drug Utilization Rates in the Middle 50 Percent of Plans</b>
MA-PD	59%	37%	83%	55%-64%
PDP	53%	38%	68%	51%-56%

Source: OIG analysis of January-June 2006 PDE data, 2007.

An analysis of MA-PD plan types shows variation across the median generic drug utilization rates, ranging from 51 percent to 66 percent. See Appendix B for a breakout of generic drug utilization rates by MA-PD plan type.

**Variation in generic drug utilization was primarily explained by variation in single-source drug prescribing**

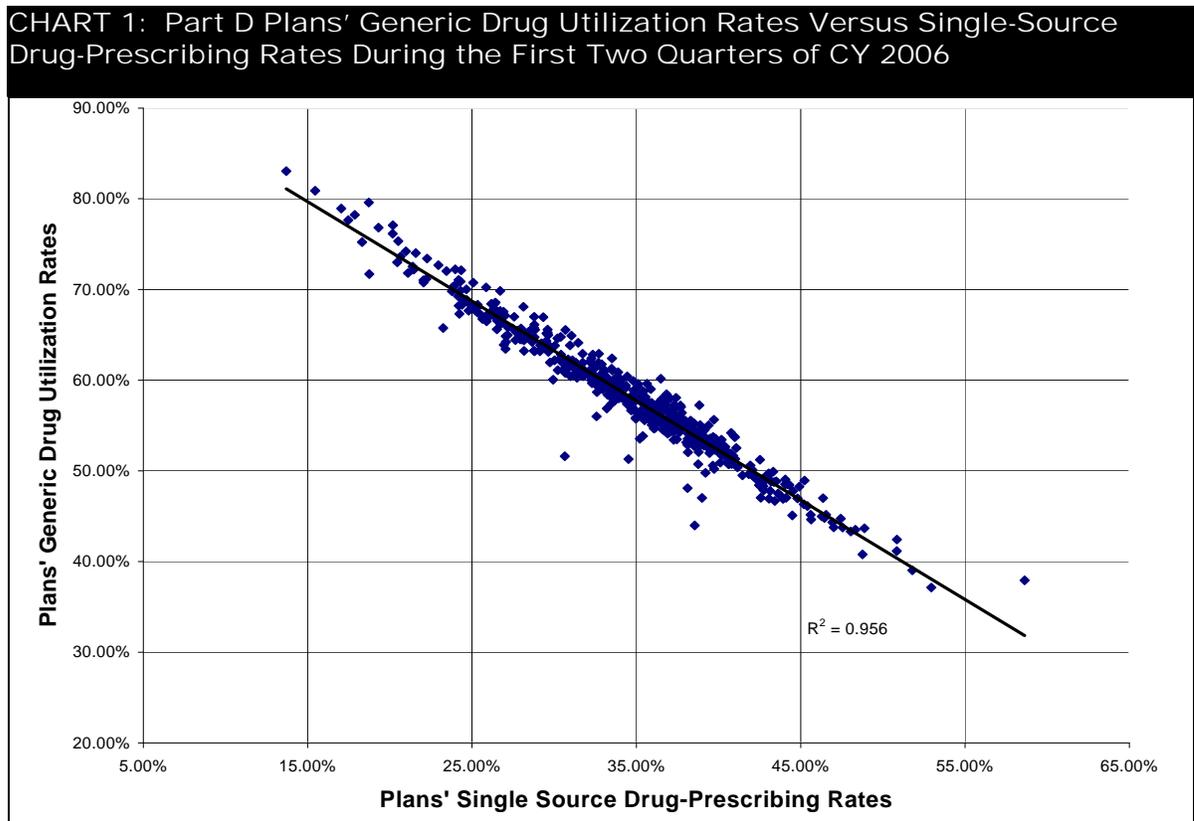
Generic drug utilization is affected by both generic drug substitution and by single-source drug prescribing. However, the relationship between generic drug substitution and generic drug utilization rates does not explain variation across Part D plans' generic drug utilization rates. Although generic drug substitution rates remained consistent across Part D plans, generic drug utilization rates varied widely from plan to plan. For example, 178 Part D plans had generic drug substitution rates of at least 90 percent but their generic drug utilization rates ranged between 38 percent and 83 percent.

On the other hand, there is a strong relationship between single-source drug prescribing and generic drug utilization. Our analysis shows that

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generic drug utilization was highest in Part D plans for which single-source drug prescribing was lowest. Of all 528 Part D plans reviewed, the Part D plan with the highest generic drug utilization rate (83 percent) also had the lowest single-source drug-prescribing rate (14 percent). Conversely, the Part D plan with the second lowest generic drug utilization rate (38 percent) had the highest single-source drug-prescribing rate (59 percent).

Chart 1 displays the relationship between Part D plans' generic drug utilization rates and single-source drug-prescribing rates under Part D for the first two quarters of CY 2006.



Source: OIG analysis of January-June 2006 PDE data, 2007

This relationship between single-source drug prescribing and generic drug utilization also held true when analyzing across MA-PD plan types. Within each MA-PD plan type, generic drug utilization was highest where single-source drug prescribing was lowest. This relationship is also true when analyzing across PDPs.

## ► C O N C L U S I O N

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Overall, Part D achieved a level of generic drug use during the first two quarters of CY 2006 that was similar to the level of generic drug use achieved by State Medicaid programs in 2004. High rates of generic drug use help reduce costs to beneficiaries and keep Part D affordable over the long term.

Despite high generic drug use overall, generic drug utilization rates varied among plans. At the low end, one Part D plan achieved a generic drug utilization rate of 37 percent, while another Part D plan achieved a rate of 83 percent. Variation in median generic drug utilization rates also occurred across different types of MA-PDs.

Variation in generic drug utilization rates appears to be a function of single-source drug prescribing and not generic drug substitution. In fact, the high levels of generic drug substitution that we found for most Part D plans suggest that Part D may have already achieved most of the growth in generic drug utilization possible through increasing generic drug substitution. Still, Part D plans with generic drug substitution rates below the median may wish to consider taking additional measures to increase generic drug substitution. Further, certain therapeutic classes show substantial variation in Part D plans' generic drug substitution rates and, thus, greater potential gains for plans with lower rates in those classes.

To achieve increases in generic drug utilization, Part D plans may realize greater gains by encouraging the prescribing of brand name multisource drugs which have generic equivalents. It is important to recognize that single-source drug prescribing caps the level of generic drug utilization attainable. In particular, Part D plans could focus on therapeutic classes with wide ranges of single-source drug-prescribing rates. For four classes—antiulcer/gastrointestinal preparations, cardiovascular preparations, lipotropics, and psychostimulants/antidepressants—plans' single-source drug-prescribing rates differed by more than 95 percentage points.

Lower single-source drug prescribing could be realized through the inclusion of multisource drugs in a Part D plan's formulary, educating prescribers, or other means such as drug utilization management tools. However, such efforts must be undertaken with caution to ensure that beneficiaries maintain access to appropriate treatment.

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In response to our draft report, CMS generally concurred with our findings. CMS noted differences between our calculation and CMS's calculation of generic drug utilization and suggested that differences may be because of CMS's inclusion of multisource brand name drugs in its measure of generic drug utilization. CMS also raised questions regarding the period under review and differences in generic drug utilization between MA-PDs and stand-alone PDPs.

With respect to the issue of different calculations of generic drug utilization, CMS suggested that we include multisource brand name drug utilization data in our report and stated that including these data would narrow the gap between our and CMS's calculation of generic drug utilization rates. We did not include multisource brand name drug utilization data in our measure of generic drug utilization because this would be inconsistent with the definition of generic drugs as used in this report. We note that the analysis presented in this report is consistent with previous work on generic drug utilization conducted by OIG.

In addition, our calculation of generic drug utilization reflects the current CMS regulatory definition for generic drugs. Pursuant to 42 CFR § 423.4, a drug is defined for the purposes of Part D as generic or brand depending on the drug application type. Multisource brand name drugs are considered brand name drugs under this definition.

The full text of CMS's comments is included in Appendix C.

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## DETAILED METHODOLOGY

### **Associating Part D Plans With Their Prescription Drug Event Drug Claims**

To determine the Part D plan associated with the Prescription Drug Event (PDE) drug claims, we used the contract number for the plan that submitted the claim, not the contract number for the plan of record. We used the contract number for the plan submitting the claim because it identifies the plan that allowed and paid for the prescription drug claim according to its formulary requirements. The plan of record reflects the plan in which the beneficiary was enrolled, which should be the same as the plan submitting the claim. In some cases, plans paid for prescription claims for beneficiaries enrolled in other plans because of out-of-date enrollment data. In such a case, the plan of record repays any plan that mistakenly paid for drugs dispensed to their enrollees.

### **Steps To Ensure the Reliability of PDE Data**

To ensure the accuracy and reliability of our generic drug use calculations, our analysis included several steps to remove PDE drug claims that could affect our calculation of the three indicators of generic use. After completing these steps, 341 million claims (84 percent of the overall claims) from 528 Medicare Part D plans remained for the analysis. Refer to Table 10 on page 25 for a summary of the types of claims removed.

These steps ensured the following:

- One claim for each dispensed prescription drug in the PDE data was analyzed. Part D plans have the ability to adjust claims within PDE data. A Part D plan can also delete a claim from PDE data. This study includes an analysis only of the last adjusted claim and omits all earlier claims that were adjusted and all deleted claims submissions. We removed the adjusted and deleted claims using a process similar to one used by the Centers for Medicare & Medicaid Services (CMS). We removed 52,438,619 claims during this step.
- Over-the-counter drugs and drugs covered under supplemental benefits, which are drugs not covered as Part D drugs, were not included in the analysis. We removed 2,967,749 claims during this step.
- No medical supply claims (e.g., diabetic supplies) were analyzed because they are not prescription drugs. We removed 19,555 claims during this step.

- No drug claims that were listed as partial fills or complete fills were analyzed because they create the potential for overstating the number of prescriptions. We removed 175,999 claims during this step.
- No drugs without product information from First DataBank or CMS were analyzed. Without product information from First DataBank or CMS, we were unable to determine the therapeutic class of the drug, whether the drug was a brand name or generic drug, and whether there were generic equivalents to the drug. We removed 2,511,589 claims during this step.
- No drug claims that were submitted to multiple plans on behalf of the same beneficiaries for the same day were analyzed. Because of the potential for misrepresenting utilization, all claims from these beneficiaries were removed from the analysis. We removed 4,306,138 claims during this step.
- No drug claims from Part D plans that were missing prescription drug claims for entire months were analyzed. The PDE data contained submissions for the first two quarters of calendar year 2006 from 547 Part D plans; however, this study retained claims from only 528 Part D plans. Nineteen Part D plans were removed because their PDE data submissions contained entire months in which no prescription drugs were claimed. We removed 328,935 claims during this step.

**Table 10: Types of Claims Removed From Generic Drug Utilization Analysis**

<b>Type of Claims Removed</b>	<b>Total Claims Removed</b>	<b>Percent of Total Claims</b>
Amended or deleted	52,438,619	13%
Over-the-counter and supplemental drugs	2,967,749	1%
Medical supplies	19,555	0%
Prescriptions filled as multiple dispensing events	175,999	0%
No drug product information	2,511,589	1%
Claims filed for beneficiaries to multiple Part D plans	4,306,138	1%
Part D plans with missing submissions	328,935	0%
<b>Total</b>	<b>62,748,584</b>	<b>16%</b>

Source: OIG analysis of January-June 2006 PDE data, 2007.

**Table 11: Median Rates for Generic Drug Utilization Indicators by Types of Medicare Advantage Prescription Drug Plans**

<b>MA-PD Plan Type</b>	<b>Median Generic Drug Substitution Rate</b>	<b>Median Single-Source Drug-Prescribing Rate</b>	<b>Median Generic Drug Utilization Rate</b>
1876 Cost Plan	90%	33%	61%
Continuing Care Retirement Community	87%	41%	51%
Health Maintenance Organization (HMO)/HMO Point of Service (HMOPOS)	90%	32%	61%
Local Preferred Provider Organization (PPO)	87%	36%	56%
Program of All Inclusive Care for the Elderly (PACE)	91%	34%	59%
Other*	89%	34%	60%
Private Fee-for-Service (PFFS)	87%	35%	57%
Provider Service Organization (PSO)	91%	32%	62%
Regional PPO	87%	37%	56%
Social Health Maintenance Organization (SHMO)	90%	27%	66%
* Includes End Stage Renal Disease, Massachusetts Health Senior Care Options, Minnesota Disability Health Options, Minnesota Senior Health Options, and Wisconsin Partnership Program plan types.			

Source: OIG analysis of January-June 2006 PDE data, 2007.

Refer to the following page for definitions of the types of Medicare Advantage prescription drug plans.

*1876 Cost Plans:* Cost plans are operated by HMOs or Competitive Medical Plans in accordance with a cost reimbursement contract under §1876(h) of the Social Security Act. Cost plans offer Part D but only as an optional supplemental benefit.

*Continuing Care Retirement Community:* These plans allow seniors to “age in place,” providing accommodations that are designed to meet their health and housing needs as these change over time.

*HMO/HMOPOS:* A type of Medicare Advantage (MA) plan in which a group of doctors, hospitals, and other health care providers agree to give health care to Medicare beneficiaries for a set amount of money.

*PPO:* An MA plan in which beneficiaries use doctors, hospitals, and providers that belong to the network. A local PPO has a service area that is less than a region and that may consist of a county, partial county, or multiple county service areas. Regional PPOs can be offered only in an MA region within the 50 States and the District of Columbia.

*PACE:* PACE serves individuals who are age 55 or older, certified by their State to need nursing home care, able to live safely in the community at the time of enrollment, and live in a PACE service area.

*PFFS:* Beneficiaries may go to any Medicare-approved doctor or hospital that accepts the plan’s payment. The insurance plan decides how much it will pay and what beneficiaries pay for the services they receive.

*PSO:* A private or public entity operated by a provider or group of affiliated providers. These types of organizations provide a substantial proportion of the health care services under the MA contract directly through the provider or affiliated group of providers.

*SHMO:* An MA plan that expands coverage for community-based long term care and is designed to keep functionally impaired older people living at home.

**AGENCY COMMENTS**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator  
Washington, DC 20201

**DATE:** OCT 19 2007

**TO:** Daniel R. Levinson  
Inspector General

**FROM:** Kerry Weems *Kerry Weems*  
Acting Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Generic Drug Utilization in the Medicare Part D Program" (OEI-05-07-00130)

Thank you for the opportunity to review and comment on the above OIG draft report evaluating generic drug utilization in the Part D program. We are pleased that the findings of the OIG report closely correlate with the Centers for Medicare & Medicaid Services' (CMS) analyses of data reported by Part D sponsors. The OIG report found that Part D achieved a high level of generic drug use in the first year of the program. Clinically appropriate generic prescribing is one of the key ways in which the Part D program is able to provide high quality coverage at a reasonable cost to both beneficiaries and the Government. We fully encourage the use of generic drugs and are glad that OIG has decided to look into this topic. In general, we concur with the findings of this study. The results of the OIG study clearly demonstrate that under the Part D program the generic substitution rate was very high and similar to the rate for State Medicaid programs. In addition, the generic dispensing rate was high for the first two quarters of 2006. Your report showed a median rate of 56 percent for Part D, while the data reported to CMS by Part D sponsors for the first two quarters of 2006 was about 59 percent.

However, upon further review and discussion, CMS found that information related to multi-source brand drugs was not included in the report. We recommend that data related to the utilization of multi-source brand drugs be added to the OIG final report. As described in the conclusion of the OIG draft report, multi-source drugs offer the opportunity to dispense a generic drug. Part D sponsors include these drugs in the data they report to CMS. CMS believes incorporating this type of utilization accurately depicts the prescribing, dispensing, and other utilization management activities within the Part D program that help to control prescription drug costs. OIG estimated that the

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results of the multi-source drug utilization were approximately 7 percent. Including this data would narrow the gap between OIG's and CMS' generic drug utilization statistics for the same time period.

Using plan-reported data on generic dispensing rates, CMS found differences between Medicare Advantage-Prescription Drug plans (MA-PDs) and Prescription Drug Plans (PDPs), while the OIG study did not find these differences. Plan-reported data, when stratified by organization type, showed that MA-PD plans had a rate of 65.9 percent and PDPs had a rate of 56.5 percent. However, based on this data, CMS is not able to determine if these differences are driven by therapeutic classes, as identified in your study.

It is also worth noting that your study is limited to drug claims' experience for only the first two quarters of 2006. The extended transition period that was in effect through the first quarter of 2006 would likely have driven down the generic rate for that period. By extending the window of claims experience beyond the first half of 2006, the generic dispensing rate would probably have increased beyond the level you identified, as was the case with the plan-reported generic dispensing data. From quarter one through the end of the calendar year, the aggregate generic dispensing rate, based on plan-reported data, increased 1.8 percentage points from 58.5 percent in quarter one to 60.3 percent for the cumulative year.

Additionally, it is worthwhile to note that recent analysis of Part D plan-reported data from Q1-Q3 2006 found Part D generic drug utilization exceeded the national third-party generic utilization average. The 2006 national third-party generic utilization was reported as 52.6 percent, while Part D sponsors reported an average generic utilization of about 59.6 percent. CMS believes this difference is significant for Medicare beneficiaries facing escalating drug costs and could help by reducing out-of-pocket costs linked to premiums and co-payments.

Thank you again for your efforts to help gain an understanding of the utilization of generic drugs in the Medicare Part D program. The comparison to State Medicaid programs helps to show that Part D is doing well in relation to the dispensing of generic drugs, and additionally, this study helps to validate the generic dispensing data reported by Part D sponsors to CMS.



## A C K N O W L E D G M E N T S

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Thomas Komaniecki, Deputy Regional Inspector General.

This report was led by Mark Stiglitz. Other principal Office of Evaluation and Inspections staff from the Chicago regional office who contributed include Meghan Kearns. Other principal central office staff who contributed include Linda Abbott and Eddie Baker.